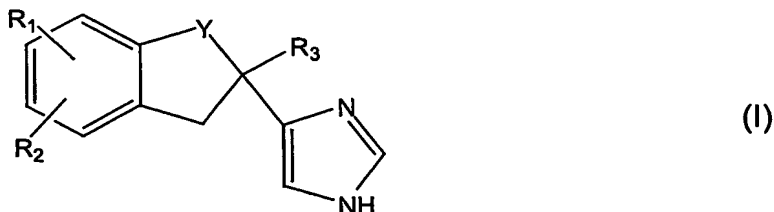


Claims

1. An oromucosal formulation comprising as an active ingredient a substituted imidazole derivative of formula (I)

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where Y is -CH₂- or -CO-, R₁ is halogen or hydroxy, R₂ is H or halogen and R₃ is H or lower alkyl, or an acid addition salt thereof, together with additives
10 conventionally used in oromucosal formulations.

2. A formulation according to claim 1 wherein the active ingredient is 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole or its acid salt, preferably hydrochloride.

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3. A formulation according to claim 1 or 2 wherein the additives are selected from solvents, preserving agents, flavouring agents and mixtures thereof.

20 4. A formulation according to claim 3 wherein the solvent is selected from ethanol, water and a mixture thereof.

5. A formulation according to claim 3 or 4 wherein the preserving agent is selected from methyl parahydroxybenzoate, propyl parahydroxy-
25 benzoate and a mixture thereof.

6. A formulation according to any of claims 3 to 5 wherein the flavouring agent is selected from aspartame, black currant and a mixture thereof.

7. A formulation according to claim 1 comprising the following components: (a) 4-(2-ethyl-5-fluoro-indan-2-yl)-1H-imidazole or its acid salt, preferably hydrochloride, (b) ethanol and water, (c) methyl
5 parahydroxybenzoate and propyl parahydroxybenzoate, and (d) aspartame and black currant.

8. A formulation according to any of the preceding claims wherein the formulation is in the form of a spray, gel, a mucoadhesive buccal tablet or
10 paste, or a sublingual tablet.

9. A formulation according to claim 8 wherein the formulation is in the form of a spray.

15 10. A process for preparing a formulation according to claim 7 comprising mixing and dissolving ethanol (96 %), purified water, methyl parahydroxybenzoate, propyl parahydroxybenzoate and aspartame at room temperature, at +15 to +25 °C; followed by adding and dissolving 4-(2-ethyl-5-fluoroindan-2-yl)-1H-imidazole hydrochloride and artificial flavour, preferably
20 black currant 502.009A, at room temperature, at +15 to +25 °C; adjusting the volume of the mixture with purified water, followed by filtering and recovering the desired spray formulation.